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newdeal®

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3. SUMMARY OF SAFETY AND EFFECTIVENESS

A. SPONSOR IDENTIFICATION

NewDeal SA
Parc d'Activitiés Garigliano
Rue de la Convention
38 200 VIENNE
FRANCE

Tél. : (33) 4 74 78 15 15
Fax : (33) 4 74 78 15 16

B. ESTABLISHMENT REGISTRATION NUMBER: 9615741

C. OFFICIAL CONTACT PERSON

Norman F. Estrin, Ph. D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac , MD 20854

Tel. : (301) 279 -2899
Fax : (301) 294-0126

D. DATE OF PREPARATION OF THIS SUMMARY: August 3, 2002

E. PROPRIETARY (TRADE) NAME: **NEWDEAL K WIRE**

F. COMMON NAME: Kirschner wire

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G. CLASSIFICATION NAME AND REFERENCE

Pin, Fixation, smooth (21 CFR, Section 888.3040)

H. PROPOSED REGULATORY CLASS: Class II

I. DEVICE PRODUCT CODE: HTY

J. PANEL CODE: 87 OR Orthopedic

K. DESCRIPTION OF DEVICE:

The **NEWDEAL K WIRE** is available in four different designs, with one or two sharp self-drilling tips either smooth or partially threaded. One part is fixed on a standard surgical power tool equipment for insertion.

The **NEWDEAL K WIRES** are made out of stainless steel within the frame of the standard NF ISO 5832-1, ASTM F138.

They are dedicated to fixation of bone fractures, bone reconstruction, as guide pins for insertion of other implants.

The range of **NEWDEAL K WIRE** includes three different diameters 1.0 mm, 1.6 and 2.5 mm and four lengths 70, 100, 150 and 200 mm.

L. INDICATIONS FOR USE: **NEWDEAL K WIRE** is indicated for use in Fixation of bone fractures, for bone reconstruction, as guide pins for insertion of other implants.

The size of the K WIRE should be adapted to the specific indication.

M. PREDICATE DEVICE: The **NEWDEAL K WIRE** is substantially equivalent to the **DePuy** Kirschner wires and Steinmann pins (K960385) and Kirschner wires and Steinmann pins from **Syntec-Taichung Medical Instruments** (K983121).

N. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS: **NEWDEAL K WIRES**, Kirschner wires, Steinmann pins from Syntec-Taichung Medical Instruments and Kirschner wires, Steinmann pins from Depuy are intended to be implanted for fixation of bone fractures, for bone reconstruction, as guide pins for insertion of other implants.

NEWDEAL K WIRES are made from 316 L stainless steel, which is the same material as the Kirschner wires and Steinmann pins from Syntec-Taichung Medical Instruments and from Depuy.

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The Kirschner wires and Steinmann pins manufactured by Depuy and Syntec-Taichung Medical Instruments and **NEWDEAL K WIRE** have comparable ranges of sizes and diameters.

O. SUMMARY OF STUDIES: **NEWDEAL K WIRES** are stainless steel wires with diameters not smaller than those featured in the predicate device systems Moreover, the **NEWDEAL K WIRES** conform to the international standard: ISO 5838-1 (1995). Testing, therefore, is not needed to demonstrate that the subject devices are substantially equivalent to other legally marketed Kirschner wires.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2002

NewDeal SA
c/o Norman F. Estrin, Ph.D.
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, Maryland 20854

Re: K022599
Trade/Device Name: NewDeal K-Wire
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: July 28, 2002
Received: August 5, 2002

Dear Dr. Estrin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

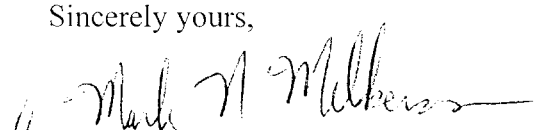
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html .

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022599

510 (k) Number (if known) :

Device Name :

Indications for Use :

NEWDEAL K WIRE is indicated for :

- use in Fixation of bone fractures,
- bone reconstruction,
- as guide pins for insertion of other implants.

The size of the K WIRE should be adapted to the specific indication.

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022599

(PLEASE DO NOT WRITE BELOW THIS LINE –CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Prescription Use OR Over –the-counter Use

(Per 21 CFR 801.109) (Optional format 1-2-96)